

MAR 27 2008

APPENDIX K

510(k) SUMMARY

K072400

**SUMMARY OF THE SAFETY AND EFFECTIVENESS FOR  
NON-STERILE, POWDER FREE BLACK NITRILE EXAMINATION GLOVES**

**Submitted For :** SGMP Company Limited, 181 Moo 6, Tambol Kampaengpetch, Rattaphum, Songkhla 90180, Thailand.

**Submitted By:** Tucker & Associates  
Official Correspondent for SGMP Co Ltd  
Janna P. Tucker, President – CEO  
198 Avenue de la D'emerale, Sparks, NV 89434-9550  
Phone No : 775-342-2612 Fax No : 775-342-2613  
E-mail: Tuckerjan@aol.com

**Equivalent Predicate Device:** POWDER FREE BLUE NITRILE EXAM GLOVES which was granted a 510(k) # K000868

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

**Device Information:**

Trade Name – Non-Sterile, Powder Free Black Nitrile Examination Gloves

Common Name - Exam gloves

Classification Name - Patient examination glove (per 21 CFR 880.6250)

Classification Information - Class I Nitrile examination glove 80LZA, powder free and meeting all the requirements of ASTM D6319-00aE3 Standard Specification for Nitrile Examination Gloves for Medical Application.

**Device Description:**

Class I Nitrile examination gloves 80LZA, powder free and meeting all the requirements of ASTM D6319-00aE3 Standard Specification for Nitrile Examination Gloves for Medical Application.

**Intended Use of Device:**

A medical glove to be worn on the hand of the health care and similar personnel to prevent contamination between health care personnel and patient.

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**Conclusion:**

The data presented indicate the Non-sterile Powder-Free Black Nitrile Examination Glove meets the following Standards:

1. ASTM D6319-00aE3, Standard Specification For Nitrile Gloves.
2. ISO 2859-1, Standard for Water Leak Test and/or ASTM D5151-06, Standard Test Method for Detection of Holes in Medical Gloves.
3. ASTM D6124-06, Standard Test Method for Residual Powder on Medical Gloves.
4. Biocompatibility Testing on White rabbits and Guinea Pigs.
5. Labeling meets FDA Specifications
6. Except for Color, this glove is equivalent to K000868.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAR 27 2008**

SGMP Company, Limited  
C/O Ms. Janna P. Tucker  
Official Correspondent/ United States Agent  
Tucker & Associates  
198 Avenue De La D' Emerald  
Sparks, Nevada 89434-9550

Re: K072400  
Trade/Device Name: Non-Sterile, Powder Free Black Nitrile Examination Gloves  
Regulation Number: 880.6250  
Regulation Name: Patient Examination Glove  
Regulatory Class: I  
Product Code: LZA  
Dated: March 11, 2008  
Received: March 13, 2008

Dear Ms. Tucker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## INDICATION FOR USE STATEMENT

Applicant : SGMP Company Limited

510K NUMBER ~~400~~ K072400

Device Name : Non-Sterile, Powder Free Black Nitrile Examination Gloves

### Indication For Use :

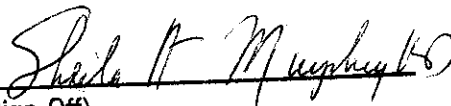
The Non-sterile Powder Free Black Nitrile Examination Gloves , is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use .....  
(Part 21 CFR 801.Subpart D)

AND / OR

Over-The-Counter.....  
21 CFR 801 Subpart C

.....  
Concurrence of CDRH , Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K072400